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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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15

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/210,031	LORINCZ ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Stephen C Siu	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 13 and 14 is/are allowed.
- 6) Claim(s) 1-12 and 15-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All b) Some \* c) None of the CERTIFIED copies of the priority documents have been:
    1. received.
    2. received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
    3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

#### Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	20) <input type="checkbox"/> Other: _____

## DETAILED ACTION

This Action is in response to Applicant's Response received October 16, 2000 (paper number 13).

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The rejection of claims 21-23 under 35 U.S.C. 103(a) as cited in the Office Action mailed July 21, 2000 (paper number 12) is withdrawn after careful consideration of Applicant's arguments and amendments.

The following issues are noted:

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-11 and 15-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 and 16-20 of copending Application No. 09/598,571. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Art Unit: 1631

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-28 of copending Application No. 09/598,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a medium comprising a cross-linking agent which is a fixative. Patent application No. 09/598,571 recites a medium comprising a fixative. The generic claim of Patent application No. 09/598,571 dominates the species claim of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1631

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-12, 15-18, 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Dunphy (US Pat No. 5,679,333; 10/21/97, filed 10/25/96).

Dunphy discloses an aqueous solution containing an alcohol (ethanol), a humectant (ethylene glycol), polyethylene glycol, a polar aprotic solvent, a chelating agent (e.g. EDTA) and an aldehyde (ethanedial) (col.3, lines 55-67 and Example 2, col.7). The fluid has a relatively acidic pH of about 4 (col.4, lines 16-18). The solution as disclosed by Dunphy contains the same ingredients as the solution recited in the claims of the instant invention and thus possesses the inherent properties of being capable of storing cells to be analyzed directly by both cytological and molecular methods. The specification of the instant application discloses the property of the solution as being capable of maintaining cells for cytological and molecular analysis and recites the composition. The composition thus recited contains the same elements as the composition of Dunphy. Thus, the composition as disclosed by Dunphy would necessarily have the same capability as the composition as claimed in the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1631

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Wainwright (US Pat No. 5370128, 12/06/94) in view of Dunphy (US Pat No 5679333, 10/21/97, filed 10/25/96).

Wainwright teaches an article of manufacture comprising a container, a lid fitting the container, and a brush (cell collecting device) for preserving a cell sample and comprising a pap unit.

Dunphy teaches a preservation fluid as above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to preserve cells utilizing the device for preserving cell samples as taught by Wainwright and to further incorporate the medium of Dunphy because the medium of Dunphy was effective in preserving animal tissues (abstract). Thus, one of ordinary skill in the art would have been motivated to utilize the preservation fluid of Dunphy in an apparatus designed to preserve cells (of Wainwright) with a reasonable expectation of success.

### ***Conclusion***

Claims 1-12, 15-27 are rejected. Claims 13 and 14 are allowable.

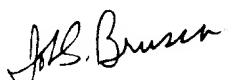
### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stephen Siu, whose telephone number is (703) 308-7522. The Examiner can normally be reached from 7:00 a.m. to 3:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see

Art Unit: 1631

37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 308-0294. Please call the Examiner at (703) 308-7522 before the transmission to expedite delivery of the fax. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephen Siu



JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER